

Tube Clamp Adapter

INSTRUCTIONS FOR USE



Introduction

This product fulfills the medical product demands according to 2017/745/EU. According to the classification criteria directives Annex IX, the product is classified as class I.

Warranty

The product is warranted from the date of purchase and the warranty period is 2 years from the date of purchase.

- In order for the warranty conditions to be valid, the practitioner Prosthetics-Orthotics specialist must be certified.
- Embreis AB does not assume any responsibility for damages caused by improper transition parts.
- Embreis AB is not responsible for the problems caused by the errors of the applicators and users.

Technical information

Art.no	Material	Dimension	Patient weight	Weight
E003A100	Aluminum	30 mm	100 kg	78 g
E003S125	Stainless steel	30 mm	125 kg	128 g
E003T125	Titanium	30 mm	125 kg	80 g

Key to symbols

The following symbols are used on labels and/or in this manual.



Manufacturer



Date of manufacture



Serial number



Attention - see information



User information



This product is in conformity with the Medical Device Regulation MDR 2017/745/EU



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Purpose and Function of Use

Tube clamp adapter E003A, E003S and E003T, used to attach the prosthetic foot to the distal connection of the modular prosthesis.

- The product is intended exclusively for lower limb fittings.
- Patient weights that the product can be used are given in technical information.



CAUTION: General safety instructions

- Do not expose the product to unallowable environmental conditions.
 - Mechanical vibrations or impacts
 - Dust, sand, excessive water retention particles
 - Sweat, urine, fresh water, salt water, acids
- If there is any visible damage, stop using the product.
- Do not hesitate by considering the repair and maintenance periods specified for the product.
- Only use the product on a single patient.
- If there is mechanical damage to the product, check its function, or contact the authorized institution. "Functional changes; It can be noticed by the deterioration of the gait, the change of the position of the prosthesis parts and / or the change of voice."

Installation

- Clean all bolts before starting the assembly.
- Use the product with parts that can be applied together.

During installation, apply the following procedures in order

1. During assembly, fully push the tube up to the stop into the intended prosthesis.
 2. Tighten the screw of the pipe adapter.
 3. Screw connection should be tightened again after 3-4 hours for control purposes.
- Check the prostheses after 30 days of use.
 - Periodic controls deemed appropriate for the implementer should be made.



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